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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,988	12/09/2005	Won-Bong Park	0056986-000004	6539

21839 7590 01/15/2009
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ALEXANDRIA, VA 22313-1404

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,988	PARK ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 5* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1 – 4, in the reply filed on November 11, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to because figure 1 of a poor quality and therefore the pertinent details of the figure cannot be made out. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top

margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: it is unclear what the text of page 25 of the specification relates to. It appears that this could be legend text for a figure, but no figure with parts “A”, “B”, "C" and "D" is present in the application.

Appropriate correction is required.

Claim Objections

4. Claims 2 and 3 are objected to because of the following informalities: a claim can only contain a single period at the end of the sentence. Both of these claims contain periods other than as the last element in the claim, at line 2 of claim 2 and the last line of claim 3. Appropriate correction is required.

5. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. One possible interpretation of claim 2 is that the excipient component comprises glucose and PV K-30, depending on the interpretation the ands, ors and multiple periods present in the claims. In claim 3, materials which can be used alone are provided, whereas claim 1, from which claim 3 depends, requires multiple ingredient in the coating. Such interpretations fail to further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 112 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The identity or full name of "PV K-30" is not described in the specification and there is no compound by this name or trade name that the Examiner was able to find in a search of the literature.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. None of the artificially processed goods of corn protein extract or artificially processed goods or derivatives of wheat protein meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. Page 12, In 18 appears to introduce a list of "processed goods produced using these" ('these' apparently referring to corn protein extract) and if so, then those artificially processed goods could meet the written description provision. The specification provides insufficient written description to support the genus of derivatives or artificially processed goods encompassed by the claim, since there is no description of the structural relationship of these derivatives or artificially processed goods provided in the specification and Applicant has not provided a description as to how the base substance may be changed while remaining a derivative or artificially processed goods.

Claim Rejections - 35 USC § 112 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. From the preamble of the claim, it appears that the list of required ingredients is intended as an enteric coating material for a composition. However, the phrase "as a coating solution" in line 5 seems to indicate that only part of the list is intended as the coating solution. In example 2-2 (p 17) of the specification, many of the listed ingredients from claim 1 are present in the core of a pharmaceutical composition that is then coated in example 3 (also on p 17). Based on location of the phrase "coating solution" in line 5, one possible interpretation of this claim is that the coating solution comprises shellac and 80% ethanol. However, the coating solution is example 3 has zein, shellac and ethanol, and based on the placement, in this alternate interpretation, the zein would be part of the core. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Generally when alcohols such as ethanol are used in coatings solution, the ethanol is present as a solvent for the application step but is then allowed to evaporate and is present in only small quantities in the final pharmaceutical product. Because of the specific amounts recited for the water and ethanol components, it is unclear if a liquid coating solution and/or dosage form is being claimed or that the recited ingredients are the starting materials for the final pharmaceutical dosage form. Therefore, the metes and bounds of the claim cannot be determined.

11. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The multiple ands, ors and the extra period in the claim make the wording of the claims such that what is being limited cannot be determined. Mannitol is identified in claim 1 as an excipient, while some of the additional ingredients recited in claim 2 are labeled with other functions in claim 1. It is unclear if the components of the entire composition is being refined in claim 2 or if alternatives for specific components of the composition are being refined. For example, one reading of the beginning of claim 2 is that instead of simply being mannitol, the excipient comprises mannitol, starch and lactose or that the "excipient" of claim 1 comprises glucose and PV K-30, instead of mannitol.

12. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It unclear what element(s) of claims 1 are being refined and or added to the composition so that the coating composition further comprises one or more of the ingredients listed in claim 3. One species of corn protein extract and its artificially processed goods is zein, which is already required to be present in claim 1. It is also unclear what is meant by the phrase "artificially processed goods" in regards to the corn and wheat proteins items present in the claim. It is unclear what the "medium chain triglycerides which has 6.about.12 carbons" means. Because of the plural "triglycerides", the implication is that more than one triglyceride is present but the

phrase "has about 6.about.12 carbons" implies that one triglyceride with the same number of carbon atoms is present.

13. Claims 1 – 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain the trademarks AVICEL®, ZEIN-DP®, AC-DI-SOL® and KOLLICOAT® MAE 30 DP. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe microcrystalline cellulose (MCC), apparently a particular type of zein protein, croscarmellose sodium and a methacrylic acid/ethyl acrylate polymer, accordingly, the identification/descriptions are indefinite.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. For the purposes of applying art below, the claims have been interpreted as a composition comprising all of the ingredients recited in claim 1, wherein the volumes of water and ethanol are not required to be present in the final composition.

18. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thosar et al. (US 6,410,054).

Thosar et al. discloses compositions with the active ingredient eplerenone (abstract). MCC, such as AVICEL® PH 101, and lactose, either individually or in combination, are the preferred diluents (col 8, ln 60 – 67). However, mannitol and/or dibasic calcium phosphate can also be used as diluents (col 8, ln 38 – 45). Hydroxypropylmethyl cellulose (HPMC) is the preferred binding agent used to impart cohesive properties to the powder blend (col 9, ln 56 – 58), although other polymers such as alginic acid and salts of alginic acid (alginates), hydroxypropylcellulose or other cellulose materials can also be used a binding agents (col 9, ln 33 – 51). The tablets can be coated for aesthetic, handling or stability purposes (col 23, ln 31 – 33) and the coating composition can be applied as a solution or suspension from solvents such as water and lower alcohols such as ethanol (col 23, ln 66 – col 24, ln 8). If a controlled release form is desired, a coating of a material such as shellac can be applied (col 24, ln 63 – col 25, ln 12), although zein can also be included in the coating composition (col 22, ln 36). The solid formulation in example 1 (col 35, ln 13 – 62) comprises active ingredient, lactose, MCC, croscarmellose sodium (AC-DI-SOL®) and HPMC to which a

coating formulation is applied. Alternatively, an oral solution in which ethanol and water are used as solvents can also be prepared (col 38, ln 40 – 63).

Thosar et al. does not explicitly prepare an example in which a composition comprising mannitol, MCC, calcium phosphate dibasic, HPMC, water, ethanol, zein and shellac with the specific amounts claimed by Applicant is prepared.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising mannitol, MCC, calcium phosphate dibasic, HPMC, water, ethanol, zein and shellac as Thosar et al. teaches that each of these elements can be included in pharmaceutical compositions. One of ordinary skill would select particular excipients based on the requirements of the composition, such as a lactose intolerant/allergic patient population. The amounts of the selected ingredients, which can alter the dissolution characteristics of the composition, and what solvents (water, ethanol, other alcohols, etc.) are used are results effective parameters. Depending on the solubility of the various ingredients chosen, the solvent system may need to be altered for optimal solubility and processing parameters (e.g., drying time). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results and the solvent(s) and quantities of the selected solvents that are required to prepare the composition.

"For an enteric coating of natural product containing lectin" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The compositions described by Sauerbier et al. and Cook use an enteric coating material and therefore composition is capable of being used for coating of lectin.

19. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauerbier et al. (US 5,252,341) in view of Cook (US 5,567,438).

Sauerbier et al. discloses a granulate prepared in the presence of alcohol and water, a binding agent and filling agent (abstract). Ethanol can be used as the alcohol in the granulation step (col 4, ln 45 – 54). Polyvinyl pyrrolidone and/or microcrystalline cellulose are preferred binding agents while lactose and or calcium hydrogen phosphate (calcium phosphate dibasic) are preferred filling agents (col 3, ln 22 – 25). To cover the unpleasant taste of the active ingredient, a polymer-containing film coating made from a material such as HPMC (col 5, ln 39 – 47). It is also advised that a sweetener such as mannitol be added to the granulate (col 6, ln 9 – 20). To further improve the taste, the granulate may be coated with a lacquer that is gastric juice resistant, such as shellac but other material such as cellulose acetate phthalate or hydroxypropylmethyl cellulose phthalate can also be used (col 6, ln 23 – 25, 30 – 34).

Sauerbier et al. does not disclose the presence of zein in the composition.

Cook discloses that shellac only dissolves in high titer alcohol or water (col 11, ln 27 – 29) and that a composite film made of zein and shellac exhibited better water barrier properties than a shellac only coating (col 11, ln 45 – 53). Inclusion of zein in the shellac coating allows for proper disintegration of the coating, regardless of any shellac aging (col 11, ln 53 – col 12, ln 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising mannitol, microcrystalline cellulose, calcium phosphate dibasic, HPMC, water shellac and ethanol as disclosed by Sauerbier et al. and to include zein in the composition. One of ordinary skill would have been motivated to add zein and would have reasonably expected success as Cook discloses that a shellac zein coating has a superior performance to that of a shellac only coating. One of ordinary skill would select particular excipients based on the requirements of the composition, such as a lactose intolerant/allergic patient population. The amounts of the selected ingredients, which can alter the taste and dissolution characteristics of the composition, and what solvents (water, ethanol, other alcohols, etc.) are used are results effective parameters. Depending on the solubility of the various ingredients choses, the solvent system may need to be altered for optimal solubility and processing parameters (e.g., drying time). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best

achieve the desired results and the solvent(s) and quantities of the selected solvents that are required to prepare the composition.

"For an enteric coating of natural product containing lectin" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The compositions described by Sauerbier et al. and Cook use an enteric coating material and therefore composition is capable of being used for coating of lectin.

20. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. (US 6,004,582) in view of Cook (US 5,567,438).

Faour et al. discloses a multi-layered osmotic device (abstract). Inert substances can be used a fillers to create the desired properties such a bulk, flow and compression characteristics and specific examples given include dibasic calcium phosphate, mannitol and MCC (col 10, ln 58 – 64). Mannitol can also be used to aid in the suspension or dissolution of active ingredients with low solubility in the use environment (col 9, ln 38 – 49). A variety of polymers can be included in the polymer coat, such as cellulose acetate phthalate and HPMC phthalate (col 7, ln 17 – 35). When it is desired that the polymer coat should be dissolved, eroded or detach from the core in the colon, materials such as HPMC, hydroxypropylcellulose and/or MCC be included (36 – 41). Shellac may also be used in the polymer coat as a material that is substantially resistant

to gastric juices (col 8, ln 3 – 14). The device prepared in example 1 (col 18, ln 4 – 59) comprises mannitol, water, HPMC and ethyl alcohol (ethanol). In example 2, a composition is prepared which contains microcrystalline cellulose, ethyl alcohol, water and HPMC (col 18, ln 60 – col 19, ln 46).

Faour et al. does not disclose the presence of zein in the composition.

Cook discloses that shellac only dissolves in high titer alcohol or water (col 11, ln 27 – 29) and that a composite film made of zein and shellac exhibited better water barrier properties than a shellac only coating (col 11, ln 45 – 53). Inclusion of zein in the shellac coating allows for proper disintegration of the coating, regardless of any shellac aging (col 11, ln 53 – col 12, ln 4).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate zein into the shellac coated osmotic device of Faour et al. which can be made using an ethanol/water solvent system, MCC and HPMC in a layer for dissolution in the colon and mannitol and dibasic calcium phosphate and mannitol as fillers for the composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Cook teaches that a shellac/zein coating has improved properties over a shellac only coating for pharmaceutical composition. One of ordinary skill would select particular excipients based on the requirements of the composition, such as a lactose intolerant/allergic patient population. The amounts of the selected ingredients, which can alter the dissolution characteristics of the composition, and what solvents (water, ethanol, other alcohols, etc.) are used are results effective parameters.

Depending on the solubility of the various ingredients choses, the solvent system may need to be altered for optimal solubility and processing parameters (e.g., drying time). Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results and the solvent(s) and quantities of the selected solvents that are required to prepare the composition.

"For an enteric coating of natural product containing lectin" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Jake M. Vu/
Primary Examiner, Art Unit 1618